PUBLIC HEALTH COUNCIL

Meeting of the Public Health Council, Tuesday, January 22, 2002, 10:00 a.m., Massachusetts Department of Public Health, 250 Washington Street, Boston, Massachusetts. Public Health Council Members present were: Dr. Howard Koh (Chairman), Mr. Manthala George, Jr., Ms. Shane Kearney Masaschi, Ms. Maureen Pompeo, and Ms. Janet Slemenda. Ms. Phyllis Cudmore, Mr. Benjamin Rubin and Dr. Thomas Sterne absent (one vacancy). Also in attendance was Attorney Donna Levin, General Counsel.

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Chairman Koh announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance, in accordance with the Massachusetts General Laws, Chapter 30A, Section 11A ½.

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The following members of the staff appeared before the Council to discuss and advise on matters pertaining to their particular interests: Ms. Sally Fogerty, Assistant Commissioner, Bureau of Family and Community Health, Ms. Anne Sheetz, Director, School Health Services Program, Bureau of Family and Community Health; Mr. Paul Hunter, Director, Office of Lead Poisoning Prevention and Control; Mr. Roy Petre, Senior Policy Analyst, Bureau of Environmental Health; Dr. Paul Dreyer, Director, Division of Health Care Quality; Mr. Paul Jacobsen, Deputy Commissioner, Department of Public Health; Ms. Joyce James, Director, Mr. Jere Page, Senior Analyst, Ms. Joan Gorga, Program Analyst, Ms. Holly Phelps, Program Analyst, Determination of Need Program.

RECORDS OF THE PUBLIC HEALTH COUNCIL:

Records of the Public Health Council Meeting of October 30, 2001 were presented to the Council. After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve Records of the Public Health Council Meeting of October 30, 2001.

PERSONNEL ACTIONS:

In a letter dated January 3, 2002, Katherine Domoto, M.D., Associate Executive Director for Medicine, Tewksbury Hospital, Tewksbury, recommended approval of the reappointments to the medical staff of Tewksbury Hospital. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees'qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Associate Executive Director for Medicine of Tewksbury Hospital, under the authority of the Massachusetts General Laws, Chapter 17,

Section 6, the following reappointments to the various medical staffs of Tewksbury Hospital be approved for a period of two years beginning January 1, 2002 to January 1, 2004:

REAPPOINTMENTS	**STATUS/SPECIALTY**	**MEDICAL LICENSE NO.**
Sanjay Kamath, M.D.	Consultant/Radiology	81929
Venkata Satyam, M.D.	Affiliate Internal Medicine	53327

In a letter dated January 12, 2002, Blake M. Molleur, Executive Director, Western Massachusetts Hospital, Westfield, recommended approval of a reappointment to the consulting medical staff of Western Massachusetts Hospital. Supporting documentation of the appointee's qualifications accompanied the recommendation. After consideration of the appointee's qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Executive Director of Western Massachusetts Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the following re-appointment to the consulting medical staff of Western Massachusetts Hospital be approved:

REAPPOINTMENT	**STATUS/SPECIALTY**	**MEDICAL LICENSE NO.**
Robert White, M.D.	Consultant/Urology	35343

In a letter dated January 12, 2002, Paul D. Romary, Executive Director, Lemuel Shattuck Hospital, Jamaica Plain, recommended approval of appointments and reappointments to the medical and allied health staffs of Lemuel Shattuck Hospital. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees' qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Executive Director of Lemuel Shattuck Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the appointments and reappointments to the medical and allied health staffs of Lemuel Shattuck Hospital be approved as follows:

PHYSICIAN APPOINTMENTS	**STATUS/SPECIALTY**	**MEDICAL LICENSE NO.**
David Atkins, M.D.	Active/Psychiatry	59921
Daniel DelVecchio, M.D.	Consultant/Plastic Surgery	56436

PHYSICIAN REAPPOINTMENTS	STATUS/SPECIALTY	MEDICAL LICENSE NO.
Mark Bankoff, M.D.	Consultant/Radiology	37557
James Burch, M.D.	Consultant/Radiology	154995
Carl Fulwiler, M.D.	Active/Psychiatry	80208
Carl Kramer, M.D.	Active/Neurology	51314
Daniel O'Leary, M.D.	Consultant/Radiology	32840
Victoria Shea, M.D.	Consultant/Psychiatry	53737

ALLIED HEALTH PROFESSIONAL – REAPPOINTMENTS	SPECIALTY	MEDICAL LICENSE NO.
Ruth Haskal, RNP	Allied Health Professional	198
Christopher Manning, RNP	Allied Health Professional	205286
Robert McMackin, EdE	Allied Health Professional	3317

In a letter dated January 22, 2002, Howard K. Koh, Commissioner, Department of Public Health, recommended approval of the appointment of Zi Zhang to Program Manager VI, Director, Health Survey Program. Supporting documentation of the appointee's qualifications accompanied the recommendation. After consideration of the appointee's qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Commissioner of Public Health, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the appointment of Zi Zhang to Program Manager VI (Director, Health Survey Program) be approved.

STAFF PRESENTATION:

"OVERVIEW OF SCHOOL HEALTH SERVICES IN MASSACHUSETTS", By Sally Fogerty, Assistant Commissioner, Bureau of Family and Community Health and Anne Sheetz, Director, School Health Services Program, Bureau of Family and Community Health:

Ms. Sally Fogerty, Assistant Commissioner, Bureau of Family and Community Health, made introductory remarks. She noted that in the 1990s the Department looked at and developed the goal that all school age children would have access to comprehensive school health services. Ms. Fogerty said, "…We have services that are within three major areas, and then we have some other specialized health programs. We have basic population-based services, which include the screening programs for vision, hearing and postural screening. We have infectious disease control and management, assessment and physical exams, medical administration, emergency medical plans. These are across the board in all schools and we work with every school district. Then we have a comprehensive enhanced school health service program…This was meant to build on those basic services. Thirdly, in multiple schools, we have expanded to provide some school-based health center services. Further, in some schools, we have developed other specialized health programs that deal with obesity, tobacco, environmental, and new models of care."

Ms. Fogerty continued, "We have worked with Medicaid, establishing the municipal Medicaid Activities Claiming Program. We provide continuing education for all school nurses, other school health personnel, and school physicians. We do leadership coordination with all of the school nurses and we provide about five hundred calls each week for consultation from the various school personnel. We have also worked to assure integration with the health care delivery system. We work with the community physicians and other providers. We have established the School Health Surveillance System. We have established standards and regulations and we have a comprehensive school health manual. We work with our Bureau of Environmental Health in monitoring the environmental quality within schools. We have over the last four to five years, developed special areas of focus. Our newest one is in the area of obesity. We have developed a focus around oral health, asthma, and maintaining linkages with the community health providers, pediatricians and also with all of the managed care organizations to implement increased standards around asthma."

Regarding behavioral and mental health, she said, "We are working jointly with the Department of Mental Health, with the Medicaid Partnership Program to really look at what are the needs in this area. We are using some bioterrorism dollars to increase access to mental health services and the coordination of mental health services and substance abuse services." Regarding violence and suicide prevention, Assistant Commissioner Fogerty noted that they have multiple activities working with DMH and working with the schools. "We have this year just received some funding and will begin to work with each school district to develop a plan around suicide prevention. Regarding alcohol, tobacco and other drug use, we have very strong tobacco cessation programs, risk taking behavior, teen pregnancy, and STD programs. This has been a major focus of most of our programs, and emergency preparedness", she said. Ms. Fogerty

noted that there are 244 local public health systems in the Commonwealth and 128 other public systems. Some are regional or vocational. There are 1,943 public school buildings and 643 non-public buildings. Presently there are 2,100 school nurses and one million, one hundred thousand students. "We know we are touching all of them in some way every day," stated Ms. Fogerty.

Ms. Anne Sheetz, Director, School Health Services Program, addressed the Council. She noted that they were fortunate in 1993 to have two million dollars allocated for School Health Services with which they established and created a best practices model for school health services. She said, "We used the best practices we had seen in schools across the Commonwealth and we defined four areas: The first is infrastructure which basically means nursing leadership: identifying goals, setting policies, improving emergency care planning and connecting with the local EMS services. The second area was supporting health education and work with DOE and Tobacco Control on this. These programs see hundreds of students every day and we try to link them with local primary care providers and health insurance programs. We had no data so we started Information Management Systems so that all programs are required to be computerized and we are moving into networking. We put this out for competitive bid in 1993 and thirty-six school districts had four years to improve in these areas. They did exceedingly well. In 1997, we still had the two million dollars and we wanted to spread it further. We chose eight of the original school districts and they were required to provide consultation to eighty-five other school districts. In FY 2000, we were given additional dollars and we increased to sixty-six enhanced programs and eleven of these consultation programs. In that year, we said all children in the community have a right to services and we required every public school district to begin to provide some services to non-publics (i.e., religion-based and independent schools). This was a major change and we felt that the skill level in the publics could be well used in the non-publics. We started screening services, immunization records, that kind of thing, in two hundred sixty-two non-public buildings."

Ms. Sheetz continued, "In FY 2001, we again had an infusion of dollars so we increased to 109 school districts with 321 non-public and charter schools in that cohort. We increased the requirements. Now every student has to have an assessment for not only immunizations but also vision, hearing, special health care needs, insurance, primary care provider, etc. at entry. We have additional requirements in the area of oral health and suicide prevention, and in the non-public, we increased from the screenings to a nursing presence two to three days a week. Currently, we partially fund 109 school districts – 565,000 plus students. We have recipient districts in those eleven consultation schools, and 77,548 students in the non-public and charter schools. There are 1,123 full-time school nurses in this cohort…We have data on 74 systems. These nurses had 5.4 million health encounters. It is a tremendous opportunity to reach a lot of students. The health encounters included mental health counseling, stress reduction, stress management, counseling about aged parents and blood pressure checks. Nursing treatment includes catheterizations, tracheostomy care and nebulizer care, central lines and ventilator care. Nursing assessment of non-descript kinds of complaints which may be mental health issues, domestic abuse, divorce in the family, and grief. Life threatening food allergies has been one of our biggest challenges this year. Last year's data shows 7.2 children per thousand had an Epi pen order. We need to gear the schools up for prevention as well as rapid response because we only have two to five minutes in many of those children to respond. First aid is a big responsibility and we have begun to track the conflict related injuries so we can get a handle on

school climates. Health education includes our work with lots of organizations. For example, the Melanoma Foundation is working on a curriculum on skin cancer prevention, and we are working with the schools in that particular area, as well as teaching the importance of cervical cancer screening and testicular screening, etc. We have seen a lot of stomach aches since September 11 occurred which should really be listed under mental health but are listed as assessments."

In closing, Ms. Sheetz noted the following services are also provided in the school setting: health screenings, case management, health education, home visits for follow-up on major problems, and collaboration with health educators for health presentations. Further, she noted that ninety percent of the enhanced districts have policies and review processes. The schools have full-time school nursing leaders, which coordinate the team of guidance counselors, teachers, administrators, school nurses etc. to assess for subtle changes in students whom may be having education or health problems. "All the schools are tobacco-free. The schools are used to refer and sign-up children for health insurance. We have helped 10,612 children sign-up for individual health care plans," she said.

Assistant Commissioner Fogerty clarified some issues. She noted that the difference between the enhanced and the school-based health centers is the school-based health center is a medical health primary care site located within a school and it provides comprehensive primary care (24 hour service, 7 days a week) service during the school year. They are affiliated with either a hospital-based clinic or a community health center…In 1990, there were ten school-based health centers and now there are 70 sites. Of the 18,031 children that registered between 1999 and 2000 at these sites, all had access to comprehensive services: 61.3% received treatment for acute or chronic health problems, 28.8 percent received counseling, 23.8% preventive services, and 9.2% case management. Of the 21% with a chronic health condition, asthma is the number one condition. In closing, she said, "We have looked at oral health, nutrition and fitness, anger management, obesity, eating disorders, violence prevention and asthma management. We have a strong linkage to health insurance, enrolling 26% of uninsured children in the schools into Mass.Health or The Childrens Medical Service Plan, the Department's plan. The majority of the services are provided by a nurse practitioner and a broad range of individuals that form a comprehensive team that is available to serve the children."

Chairman Koh, added, "…There are two wonderful sayings that apply to this whole area; first, that a child must learn to be healthy, and also must be healthy to learn; and the second saying is that kids are 20% of the population but 100% of our future. This program is an investment in our future and an investment of which we can be very proud. You have presented data showing over 5 million school encounters a year. These are efforts that integrate school and health. It provides health support for needy children where they are. We are particularly proud of the links to health care and to primary care. The school-based health centers also provide needy children a medical home. These are all tremendous landmarks of a successful collaborative effort between schools and health systems across the state and we are very proud of it." A brief discussion followed by the Council.

PROPOSED REGULATIONS:

INFORMATIONAL BRIEFING ON PROPOSED AMENDMENTS TO 105 CMR 460.000, LEAD POISONING PREVENTION AND CONTROL REGULATIONS: MODIFICATION OF DEFINITION OF DANGEROUS LEAD IN PAINT, LEAD DUST AND CLEARANCE LEVELS AND OTHER MATTERS:

Mr. Paul Hunter, Director, Childhood Lead Poisoning Prevention Program, presented the proposed changes to 105 CMR 460.000. He said, "The proposed amendments result from changes in the federal statute and regulation, particularly those of the federal Housing and Urban Development Office. We have an obligation to assure that Massachusetts continues to receive federal housing assistance, that our regulations are as protective as those of the federal agency. What we are proposing in these amendments is to lower the definition of the dangerous level of lead paint slightly from 1.2 to 1.0 milligrams per centimeter square, and to lower the lead dust clearance standards, those levels that have to be attained after any lead abatement occurs. We will be lowering those for window wells and window sills basically by fifty percent, from eight hundred to four hundred for wells and five hundred to two fifty for sills, and slightly lowering the dust clearance level on floors from fifty to forty (unigrams) per square foot. This will assure that Massachusetts can continue to receive federal funding. New federal regulations took effect on January 11th that require all units of housing receiving federal assistance must address lead paint and must meet these standards. One other minor change that we have made is to the prerequisite training of risk assessors, who are those individuals that perform both lead inspections and dust lead clearance. Previously, an inspector had to have completed seventy-five inspections prior to taking risk assessment training, and now we are allowing them to take the training and then meet the prerequisite after the training. Over the last several months, we have trained over a hundred and ninety-two licensed lead inspectors to be eligible to become risk assessors, to assure that the Commonwealth has an adequate capacity of risk assessors to meet the demand of the federally funded programs."

Mr. Roy Petre, Senior Policy Analyst, Bureau of Environmental Health Assessment, addressed the Council. He said, "…One amendment presents and clarifies the legal status of a lead inspection and risk assessment. And this clarification is important because it is going to help prevent misconceptions concerning the nature of that inspection and risk assessment, and reluctance on the part of some people to have a lead inspection performed. As a protection measure, a proposed amendment will require an additional risk assessment and reinspection anytime a family reoccupies a residence before the final compliance reinspection. This will be another important safety check in our compliance process. Finally, another amendment expands the prohibition against conflicts of interest for lead inspectors to include subcontracted deleading work. Those are the amendments that we are proposing. There are some additional amendments that are streamlining in nature, and reduce some redundancies that we identified in the regulations.

NO VOTE/INFORMATION ONLY

INFORMATIONAL BRIEFING ON PROPOSED LICENSURE REGULATIONS FOR ANGIOPLASTY AND CARDIAC SURGERY QUALITY MONITORING AND PATIENT OUTCOME DATA REQUIREMENTS AND RELATED AMENDMENTS TO THE

HOSPITAL LICENSURE REGULATIONS:

Dr. Paul Dreyer, Director, Health Care Quality, presented an informational briefing on proposed regulations for angioplasty and cardiac surgery quality monitoring and patient outcome data requirements etc.. He said, "…These regulations are the result of legislation in the FY 2000 State Budget, Chapter 159 of the Acts of 2000, that mandated the development of new community cardiac surgery programs. That was in section 429. Companion Section 428 created a Cardiac Quality Commission to make recommendations about data collection so that we could be assured that any new community program, in fact all cardiac surgery programs, were producing high quality outcomes. The Executive Summary of the Commission's report has been attached for your review. Essentially, what these regulations require is that all hospitals collect two data sets. The data set developed by the Society for Thoracic Surgeons, that's called the STS Data Set, and the NCDR Data Set, which is the National Cardiovascular Data Registry, which is a trademark product of the American College of Cardiology, and both report those data sets to the respective registries, which are national data registries, and also submit those data to the Department through what we are calling a Data Analysis Center, which is an entity with which the Department contracts. The notion then is that the Data Analysis Center will produce hospital specific outcome reports, using appropriate statistical methodologies. What these data sets allow is appropriate case mix adjustment of the data so that the hospital specific outcome reports will enable folks to compare performance of the hospitals with some confidence that appropriate clinical variation among and between hospitals has been appropriately accounted for. The purpose of this presentation today is to announce to the Council that these regulations will be going out to public hearing. We have already notified hospitals that this is going to be happening and we have asked them to be prepared to collect data back to this past January 1st. Many hospitals are already participating in these registries and I know that many hospitals are moving to comply with that request. The regulation obviously will be effective on the date that it is promulgated…"

NO VOTE/INFORMATION ONLY

EMERGENCY REGULATION: REQUEST FOR APPROVAL OF EMERGENCY AMENDMENTS TO 105 CMR 950.000: CRIMINAL OFFENDER RECORD CHECKS:

Deputy Commissioner Paul Jacobsen explained the rollover request of the emergency regulation regarding criminal offender record checks. He said in part, "…On November 21, 2000 the Department of Public Health adopted on an emergency basis the first set of regulations entitled 'Criminal Offender Record Checks – 105 CMR 950.000. This set of regulations was adopted as final on August 21, 2001. The Department had to modify one portion of the regulations that were adopted as final in August 2001, to comply with the findings of the court in Cronin et al v. O'Leary. As a result, on October 30, 2001 (effective date of October 10, 200l), the Public Health Council approved a request to adopt revised Criminal Offender Record Checks regulations on an emergency basis….A couple of months later, a legislative directive in the budget for Fiscal Year 2002, language concerning CORI reviews by programs funded by the Executive Office of Health and Human Services (EOHHS) and its agencies, was enacted by the legislature on December 1, 2001. EOHHS has requested that the agencies keep their respective regulations, as promulgated up to this point in time while a consistent approach for compliance

with this new language is developed. Consequently, the Public Health Council is requested to adopt these regulations on an emergency basis for another 90 days, effective January 10, 2002, while these efforts are undertaken by DPH and other EOHHS agencies."

Deputy Commissioner Jacobsen stated further, "Since the Council had no scheduled meeting before today, January 22nd, notice of the renewed adoption of these regulations was filed with the Secretary of State's Office on January 10, 2002 on the basis that Council authorized the regulations to be in effect until it could act upon their status. Failure to file the regulations on January 10th would have resulted in a lapse of the new emergency revisions to the regulations which the Council had not intended nor authorized. Moreover, the lapse would have resulted in a reversion to regulations that are out of compliance with the court's orders in the Cronin case.

After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve the **emergency adoption of 105 CMR 950.000: Criminal Offender Record Check** Regulations; that a copy be forwarded to the Secretary of the Commonwealth for promulgation; and that a copy of the emergency regulations (Attachment I), Language from the EOHHS FY 2002 Budget Line Item (Attachment II) and the memorandum to the Commissioner and Council are attached and made a part of this record as **Exhibit Number 14,726**.

BACKGROUND INFORMATION ON 105 CMR 950.000:

The regulations establish four categories of criminal offenses that might show up on a CORI check: lifetime presumptive disqualification, ten-year presumptive disqualification, five-year presumptive disqualification and discretionary disqualification:

- In the event that a candidate for employment or a volunteer or trainee position has a lifetime presumptive disqualification, that candidate will have an opportunity for consideration for employment involving potential unsupervised contact with clients. There is no set time passage that makes a lifetime presumptive disqualification candidate eligible for consideration, as there is with the 10 and 5-year presumptive categories. A candidate with a lifetime presumptive disqualification, however, may be considered for employment upon a positive assessment by a qualified mental health professional or a criminal justice official that the individual does not pose an unacceptable risk of harm to the persons served by the program. In addition, the hiring authority must also conduct a review to determine that the candidate does not pose a danger to clients.

- Candidates with a 5 or 10 year presumptive disqualification may be eligible for positions involving potential unsupervised contact with clients, but only after the 5 or 10 year period has passed or the candidate's criminal justice official or a qualified mental health professional concludes in writing that the candidate does not pose an unacceptable risk of harm. Further, the hiring authority must then conduct a review to determine that the candidate does not pose a danger to clients.

- An individual with a discretionary disqualification may be eligible for a position involving potential unsupervised client contact only after the employer conducts a review to determine

that the candidate does not pose a danger to clients.

- The regulations contain a waiver provision, which allows the Department to grant an exemption from the requirements relating to the 10 and 5 year presumptive categories to a vendor agency program when the Department determines that the exemption is warranted on the basis of consideration of the following criteria:

    - The service needs and level of vulnerability of the clients served by the program

    - The potential benefits and risks to those clients as a result of the exemption

    - The hiring authority's capacity to perform the review required under the discretionary exemption provisions of the regulations

Note: Programs that serve 16 years of age or under or a population that is primarily 65 years of age or older are not eligible for the waiver. This waiver provision does not apply to individuals convicted of a crime in the presumptive lifetime disqualification category.

Cronin et al v. O'Leary:

Prior to adoption of the emergency regulations by the Department of Public Health and other EOHHS agencies, several individuals challenged the validity of the EOHHS policy on criminal background checks, which predated the regulations, and served as the model for the regulations. The court ruled that a mandatory lifetime disqualification from employment in EOHHS human service deprived plaintiffs of a constitutional liberty interest. It further held that individuals convicted of crimes on the mandatory list were entitled to an opportunity to rebut the presumption that they pose too great a danger to work with human service clients and ordered EOHHS to provide plaintiffs a fair opportunity by October 12, 2001.

DETERMINATION OF NEED PROGRAM:

CATEGORY 2 APPLICATIONS (FOUR COMPARABLE FOR PET SCANNERS):

PROJECT APPLICATION NO. 4-3993 OF BRIGHAM AND WOMEN'S HOSPITAL; PROJECT APPLICATION NO. 4-3994 OF BETH ISRAEL DEACONESS MEDICAL CENTER; PROJECT APPLICATION NO. 4-3995 OF CHILDREN'S HOSPITAL MEDICAL CENTER; AND PROJECT APPLICATION NO. 4-4886 OF SHIELDS IMAGING OF MASSACHUSETTS, LLC:

Ms. Joyce James, Director, Determination of Need Program made introductory remarks on the four PET scanner applications. She noted that there are four applications for Positron Emission Tomography Services (PET). PET is a non-invasive diagnostic technique that enhances the diagnosis and treatment of patients with certain diseases. She further noted that when DoN staff

refer to minimum number of scans, they are referring to the 1,220 scans recommended by the PET guidelines, adopted by the Council in 1998, to support a PET scanner. The guidelines did not indicate the number of PET scanners to serve the needs of Massachusetts population because of the ongoing research of PET applications.

Brigham and Women's Hospital:

Ms. Joan Gorga, Program Analyst, Determination of Need Program, presented the application of Brigham and Women's Hospital, a tertiary care hospital located in Boston. Ms. Gorga said, "The applicant is seeking approval to provide PET scanning through the purchase of a PET body scanner to be located in the Division of Nuclear Medicine on Level 1 of the hospital. The application was reviewed against the factors of the DoN Guidelines for PET. The recommended MCE of the Brigham and Women's project is 1,782,000 dollars, which will be funded through an equity contribution from the applicant's unrestricted funds. The applicant has projected that the scanner will exceed the minimum annual volume scans required in the guidelines. Staff found that in response to community initiatives, Brigham and Women's has offered to provide a total of 100,000 dollars over a five-year period to recruit and support individuals in the Boston community for training as radiology technicians and to carry out the priorities of CHNA with a series of mini grants. Two Ten Taxpayer Groups registered in connection with the application. One Ten Taxpayer Group, which filed in connection with all four of the applications before the Council today submitted comments which were addressed in the staff summaries. In conclusion, staff recommends approval of the application Project No. 4-3993 with the conditions as indicated in the staff summary, which have been agreed to by the applicant. Staff would be glad to answer questions on the project. Representatives of the applicant are here today to answer questions and representatives of the TTG may also be here, but they have indicated they will not address the Council today."

Beth Israel Deaconess Medical Center:

Ms. Holly Phelps, Program Analyst, Determination of Need Program, presented the Beth Israel Deaconess Medical Center application to the Council. Ms. Phelps said, "The recommended maximum capital expenditure for the project is 1,955,000 dollars. The applicant is proposing scan volume in excess of the 1,250 required by the guidelines, and I would like to say that they provided a comprehensive and convincing case by diagnosis through a very thorough review and presentation of the medical literature. The BI Deaconess application also demonstrates that they have met all the other review factors of the guidelines. For their community health initiative, they are proposing $100,000 over a five-year period that will go to a mini grant program, that will address the priorities established by the community health network. The RFP process will be administered by the CHNA. Staff is recommending approval of this project with the conditions listed in the staff summary."

Children's Hospital Medical Center:

Ms. Joan Gorga, Program Analyst, presented the Children's Hospital Medical Center application to the Council. Ms. Gorga said, "Children's Hospital is a tertiary care hospital located in Boston and is seeking approval to provide PET scanning through the purchase of a PET body scanner to be located in the Division of Nuclear Medicine on the second floor of the hospital. The application was reviewed against the DoN application factors and the DoN PET Guidelines and were met. The recommended maximum capital expenditure is 2,304,195 dollars which, will be funded through an equity contribution from the applicant's restricted funds. The applicant has projected that the scanner will exceed the minimum annual volume of 1,250 scans required in the guidelines. Staff found that, in response to the community health initiatives requirement, Children's has offered to provide a total of 150,000 dollars over a five-year period for pediatric asthma prevention in Boston and CHNA #19. One Ten Taxpayer Group registered in connection with the application and its comments were reviewed in my presentation on the Brigham and Women's Hospital. In conclusion, staff recommends approval of the application, Project No. 4-3995, with the conditions indicated in the staff summary, which have been agreed to by the applicant. Staff would be glad to answer questions on the project and representatives of the applicant are here to answer any questions."

Shields Imaging of Massachusetts, LLC:

Mr. Jere Page, Senior Analyst, Determination of Need Program, presented the Shields Imaging of Massachusetts application for PET. Mr. Page stated, "Shields Imaging will provide PET services through acquisition of a mobile PET body scanner. It will be provided at three host hospitals: South Shore Hospital in Weymouth; UMASS Memorial Medical Center, Worcester, and Baystate Medical Center, Springfield. The recommended maximum capital expenditure is 2.5 million dollars, which will be funded in part through an equity contribution of $600,000 dollars, and the remaining amount will be financed through the equipment vendor, Siemens Medical Systems. Staff found that the proposed mobile service will exceed the minimum volume requirements, as well as provide a more accessible PET service to patients in the areas served by the three host hospitals, which lack DoN approved PET services. The community initiatives amount is 130,000 dollars over five years to fund a grant-based cancer and heart disease prevention program. The Ten Taxpayer groups on the project have declined to address the Council. We are recommending the Shields Mobile PET Project with the conditions listed on pages 13 and 14 of the staff summary be approved."

Brigham and Women's Hospital declined to address the Council. Ms. Joan Pickett, Director, Strategic Planning, Beth Israel Deaconess Medical Center commented. She said, "We are pleased to be here and pleased with the staff's recommendation to approve our DoN application for a PET unit." Dr. Robert Kane, Associate Chief of Radiology, Beth Israel Deaconess, said, "I just want to emphasize the patient care needs that are involved in this application. PET is becoming increasingly important in diagnosis and assessment of therapy in cancer patients. This has been recognized by the FDA, by HCFA, and by the medical community and radiologic community. We now have access to a PET scanner only at the Dana Farber, which is close, but the wait is three and a half weeks to get an appointment. Therapeutic decisions are influenced by PET scan information. A patient may go to surgery or not based on findings of a PET scan. Having to wait three or four weeks for the information is difficult. We think there is definitely a need for another scanner for our patients and we are very pleased the staff has concurred with us

and we thank you for considering our application." Children's Hospital declined to address the Council.

Chairman Koh, noted that the Council received comments from Congressman Richard Neal, dated January 17, 2002, in which he expresses full support of Shields Imaging and their application. In addition, Dr. Robert Dann of Baystate Medical Center submitted an e-mail in support of the Shields Imaging application. Ms. Katie Putney, Chief of Staff for Senator Robert Hedlund of the Plymouth Norfolk District, read a letter of support for Shields Imaging into the record, dated July 24, 2001. An excerpt from the letter states, "…The availability of the mobile PET scanner will allow South Shore Hospital physicians to diagnose cancer earlier and plan more precise treatment for South Shore residents who must now travel to Boston for a PET scan. Allowing South Shore Hospital to have this service would greatly contribute to reducing mortality from cancer and allow better quality of life for patients undergoing treatment. Considering all the benefits this would bring to patients and their families, we urge your approval of the DoN application by Shields Imaging of Massachusetts." The letter was also signed by Senator Ronald Mariano, 3rd Norfolk District, Senator Michael Morrissey, Norfolk/Plymouth District, Representative Garrett Bradley, 3rd Plymouth District, Senator Robert Havern, Plymouth/Norfolk District, Representative Francis Marini, 6th Plymouth District, Representative James Murphy, 4th Norfolk District, Representative Robert Nyman, 5th Plymouth District, Representative Joseph Sullivan, 5th Norfolk District, Representative Kathleen Teahan, 7th Plymouth District, and Representative Frank Hynes, 4th Plymouth District.

Thomas Shields, founder and CEO of Shields Imaging of Massachusetts, LLC, accompanied by Dr. Tanya Lingos, Medical Director, South Suburban Oncology Center, Quincy, and David Hannon, President of South Shore Hospital, said in part, "…If you approve our application, we will run a facility that will make you very proud of the kind of service that you expect your citizens to receive and that no person will ever be denied care for lack of the adequacy of means to pay for that service. We have a history of some twenty years with the Department of having made that contract, and we have always fulfilled it." No Ten Taxpayer Group testified.

After consideration upon motion made and duly seconded, it was voted: (Chairman Koh, Mr. Manthala George, Jr., Ms. Shane Kearney Masaschi, and Ms. Janet Slemenda in favor; Ms. Maureen Pompeo abstaining) to approve **Project Application Number 4-3993 of Brigham and Women's Hospital,** based on staff findings, a summary is attached and made a part of this record as **Exhibit Number 14,727,** with a maximum capital expenditure of $1,782,000 (February 2001 dollars), and first year incremental operating costs of $1,586,557 (February 2001 dollars). As approved, the application provides for a Positron Emission Tomography (PET) Service through acquisition of a PET body scanner to be located in its Division of Nuclear Medicine. This Determination is subject to the following conditions:

1. The applicant shall accept the maximum capital expenditure of $1,782,000 (February 2001 dollars) as the final cost figure, except for those increases allowed pursuant to 105 CMR 100.751 and 752.

2. BWH shall contribute 100% in equity toward the final approved MCE.

3. The applicant shall not consider ability to pay or insurance status in selecting or scheduling patients for PET services.

4. The applicant will provide $100,000, over a five-year period for support of scholarships and academic support for the training of radiology technicians in the Boston community and for mini-grants to further the priorities of the CHNA. Funding for these initiatives will begin upon implementation. The specific service initiatives and associated funding are described below:

    - **Support for Radiology Technician Training:** $10,000 each year for 5 years for outreach to the Boston Community to recruit and support individuals for scholarships and academic support to attend community colleges to train radiology technicians with recruitment done with the input and collaboration of the CHNA.

    - **CHNA mini-grants:** $10,000 each year for 5 years for a mini-grants program for initiatives to carry out the priorities of the CHNA. The funds shall be awarded to providers through an RFP process to be developed, administered and evaluated by the Alliance for Community Health (CHNA 19) and a representative of BWH shall be included in the grant making process.

Staff's recommendation was based on the following findings:

1. BWH proposes to provide PET services through acquisition of a PET body scanner and dedicated computers to be located in its Division of Nuclear Medicine.

2. The project meets the requirements of the health planning process consistent with the Guidelines for Positron Emission Tomography (Guidelines).

3. BWH has demonstrated demand for the proposed PET unit as discussed under the Health Care Requirements Factor of the Staff Summary.

4. The project, with adherence to a certain condition, meets the operational objectives of the Guidelines.

5. The project meets the compliance standards of the Guidelines.

6. The recommended maximum capital expenditure of $1,782,000 (February 2001 dollars) is reasonable, compared to a similar, previously approved project.

7. The recommended operating costs of $1,586,557 (February 2001 dollars) are reasonable compared to a similar, previously approved project.

8. The project is financially feasible and within the financial capability of the applicant.

9. The project meets the relative merit provisions of the Guidelines.

10. The project, with adherence to a condition, meets the community health service initiatives of the DoN Regulations.

11. The Lisa Breen Ten Taxpayer Group and the Mark Taylor Ten Taxpayer Group registered in connection with the project. The Taylor Group submitted comments which indicated there was excess capacity at New England PET in Methuen, a DoN exempt physician practice. Staff notes that this excess capacity had not reduced waiting times at existing Boston PET facilities and that BWH patients had chosen to receive treatment and diagnostic services at BWH and were unlikely to chose to receive PET services in Methuen.

12. This is one of four comparable applications filed by BWH, Children's Hospital Medical Center, Beth Israel Deaconess Medical Center, and Shields Imaging of Massachusetts. When considered alone, all of the applications are capable of being approved, since each has demonstrated demand for PET services. A detailed comparability analysis was not undertaken since the four applications meet the review factors of the PET Guidelines.

After consideration, upon motion made and duly seconded, it was voted: (Chairman Koh, Mr. Manthala George, Jr., Ms. Shane Kearney Masaschi, and Ms. Janet Slemenda in favor; Ms. Maureen Pompeo abstaining) to approve **Project Application Number 4-3994 of Beth Israel Deaconess Medical Center,** based on staff findings, a summary is attached and made a part of this record as **Exhibit Number 14,728,** with a maximum capital expenditure of $1,955,000 (February 2001 dollars), and first year incremental operating costs of $1,600,398 (February 2001 dollars). As approved, the application provides for provision of a Positron Emission Tomography (PET) Service through acquisition of a PET body scanner and associated renovation to be located in the Nuclear Medicine Section within the Radiology Department. This Determination is subject to the following conditions:

1. The applicant shall accept the maximum capital expenditure of $1,955,000 (February 2001 dollars) as the final cost figure, except for those increases allowed pursuant to 105 CMR 100.751 and 100.752.

2. BIDMC shall contribute 100% in equity toward the final approved MCE.

3. The Applicant shall not consider ability to pay or insurance status in selecting or scheduling patients for PET services.

4. The applicant will provide $100,000 (February 2001) over a five year period ($20,000 annually) for a mini-grant(s) program for prevention services or programs. The funds shall be awarded to providers through an RFP process to be developed, administered and evaluated by the Alliance for Community Health (CHNA 19).

Staff's recommendation was based on the following findings:

1. BIDMC proposes to provide Positron Emission Tomography (PET) services through acquisition of a PET body scanner to be located in the Nuclear Medicine Section within the

Radiology Department.

2. The project meets the requirements of the health planning process consistent with the Guidelines.

3. BIDMC has demonstrated demand for the proposed PET unit as discussed under the Health Care Requirements factor of the Staff Summary.

4. The project, with adherence to a certain condition, meets the operational objectives of the guidelines.

5. The project meets the compliance standards of the Guidelines.

6. The recommended maximum capital expenditure of $1,955,000 (February 2001 dollars) is reasonable, compared to a similar, previously approved project.

7. The recommended operating costs of $1,600,398 (February 2001 dollars) are reasonable compared to a similar, previously approved project.

8. The project is financially feasible and within the financial capability of the applicant.

9. The project meets the relative merit provisions of the Guidelines.

10. The project, with adherence to a condition, meets the community health service initiatives of the DoN Regulations.

11. The Mark Taylor and Stephen Weiner Ten Taxpayer Groups registered in connection with the project and the Taylor Group submitted comments which indicated there was excess capacity at New England PET in Methuen, a DoN exempt physician practice. Staff noted that this excess capacity had not reduced waiting times at existing Boston PET facilities and that BIDMC patients had chosen to receive treatment and diagnostic services at BIDMC and were unlikely to chose to receive PET services in Methuen.

12. This is one of four comparable applications filed by Beth Israel Deaconess Medical Center, Brigham and Women's Hospital, Children's Hospital Medical Center, and Shields Imaging of Massachusetts. When considered alone, all of the applications are capable of being approved, since each has demonstrated demand for PET services. A detailed comparability analysis was not undertaken since the four applications meet the review factors of the PET Guidelines.

After consideration, upon motion made and duly seconded, it was voted: (Chairman Koh, Mr. Manthala George, Jr., Ms. Shane Kearney Masaschi, and Ms. Janet Slemenda in favor; Ms. Maureen Pompeo abstaining) to approve **Project Application Number 4-3995 of Children's Hospital Medical Center,** based on staff findings, a summary is attached and made a part of this record as **Exhibit Number 14,729,** with a maximum capital expenditure of $2,304,195 (February 2001 dollars), and first year incremental operating costs of $1,604,000 (February 2001

dollars). As approved, the application provides for provision of a Positron Emission Tomography (PET) Service through acquisition of a PET body scanner to be located in its Division of Nuclear Medicine. This Determination is subject to the following conditions:

1. The applicant shall accept the maximum capital expenditure of $2,304,195 (February 2001 dollars) as the final cost figure, except for those increases allowed pursuant to 105 CMR 100.751 and 100.752.

2. Children's shall contribute 100% in equity toward the final approved MCE.

3. The applicant shall not consider ability to pay or insurance status in selecting or scheduling patients for PET services.

4. The applicant will provide community initiatives of $150,000 payable in five installments for pediatric asthma prevention programs in Boston and CHNA 19. Funding for these initiatives will begin upon project implementation.

The specific service initiatives and associated funding are described below:

- **"Kids with Asthma" program**; $15,000 each year for five years for this collaborative program with the Boston Public Health Commission which promotes physical activity for children and adolescents with asthma.

- **Five mini-grants** of $3,000 each for five years to address problems with asthma distributed throughout CHNA 19 as determined by the CHNA review Committee.

Staff's recommendation was based on the following findings:

1. Children's proposes to provide Positron Emission Tomography (PET) services through acquisition of a PET body scanner and dedicated computers to be located in its Division of Nuclear Medicine.

2. The project meets the requirements of the health planning process consistent with the Guidelines for Positron Emission Tomography (Guidelines).

3. Children's has demonstrated demand for the proposed PET unit as discussed under the Health Care Requirements factor of the Staff Summary.

4. The project, with adherence to a certain condition, meets the operational objectives of the Guidelines.

5. The project meets the compliance standards of the Guidelines.

6. The recommended maximum capital expenditure of $2,304,195 (February 2001 dollars) is reasonable, compared to a similar, previously approved project.

7. The recommended operating costs of $1,604,000 (February 2001 dollars) are reasonable compared to a similar, previously approved project.

8. The project is financially feasible and within the financial capability of the applicant.

9. The project meets the relative merit provisions of the Guidelines.

10. The project, with adherence to a condition, meets the community health service initiatives of the DoN Regulations.

11. The Mark Taylor Taxpayer Group registered in connection with the project and submitted comments which indicated there was excess capacity at New England PET in Methuen, a DoN exempt physician practice. The applicant has indicated that pediatric PET is best handled at a facility with experience in pediatric PET imaging. Therefore the Methuen facility would not be appropriate for the Children's patients.

12. This is one of four comparable applications filed by Children's Hospital Medical Center, Brigham and Women's Hospital, Beth Israel Deaconess Medical Center, and Shields Imaging of Massachusetts. When considered alone, all of the applications are capable of being approved, since each has demonstrated demand for PET services. A detailed comparability analysis was not undertaken since the four applications meet the review factors of the PET Guidelines.

After consideration, upon motion made and duly seconded, it was voted: (Chairman Koh, Mr. Manthala George, Jr., Ms. Shane Kearney Masaschi, and Ms. Janet Slemenda in favor; Ms. Maureen Pompeo abstaining) to approve **Project Application Number 4-4886 of Shields Imaging of Massachusetts, LLC,** based on staff findings, a summary is attached and made a part of this record as **Exhibit Number 14,730,** with a maximum capital expenditure of $2,564,000 (February 2001 dollars), and first year incremental operating costs of $3,135,291 (February 2001 dollars). As approved, the application provides for provision of a Positron Emission Tomography (PET) Service through acquisition of a mobile PET body scanner and related equipment. The services will be provided at three host sites: South Shore Hospital in Weymouth, UMass Memorial Medical Center in Worcester, and Baystate Medical Center in Springfield. This Determination is subject to the following conditions:

1. Shields Imaging of Massachusetts, LLC shall accept the maximum capital expenditure of $2,564,000 (February 2001 dollars) as the final cost figure, except for those increases allowed pursuant to 105 CMR 100.751 and 752.

2. Shields Imaging of Massachusetts, LLC shall contribute 23.4% in equity ($600,000 in February 2001 dollars) toward the final approved MCE.

3. Prior to implementation of the mobile PET service, Shields Imaging of Massachusetts, LLC will obtain a certificate of registration from the Department's Radiation Control Program.

4. Prior to implementation of the mobile PET service, Shields Imaging of Massachusetts, LLC shall secure a written agreement with a provider of radiopharmaceuticals to ensure that a

reliable supply will be available for the service.

5. Shields Imaging of Massachusetts, LLC shall not consider ability to pay or insurance status in selecting or scheduling patients for PET services.

6. Shields Imaging of Massachusetts, LLC shall provide a total of $130,000 (February 2001 dollars) over five years at $26,000 per year to fund grant-based prevention programs that support the Healthy People 2010 leading indicators, particularly cancer and heart disease prevention. Each Community Health Network Area (CHNA) associated with the three host sites, including South Shore Hospital (CHNA #20), UMASS Memorial Medical Center (CHNA #8), and Baystate Medical Center (CHNA #4), will award its share of the funding through community grants to community-based health and wellness organizations, based upon recommendations by the Grant Review Committees of each CHNA. All grants will be awarded by a fiscal agent approved by each CHNA. Specific details of the grant award process will be determined through further consultation with the Department and each CHNA. Shields will file reports, as specified by the Department, detailing the frequency, content, and formalities of programming resulting from the grants and evaluations of the programming's effect on the health of service area residents. Such reports shall be filed annually or more frequently if so determined by the DoN Program Director. Funding for this initiative will begin upon project implementation, and notification to the Department's Office of Healthy Communities.

Staff's recommendation was based on the following findings:

1. Shields Imaging of Massachusetts, LLC proposes to provide Positron Emission Tomography (PET) services through acquisition of a mobile PET body scanner and ancillary equipment, including a trailer. The services will be provided at three host sites: South Shore Hospital in Weymouth, UMass Memorial Medical Center in Worcester, and Baystate Medical Center in Springfield.

2. The project meets the requirements of the health planning process consistent with the Guidelines for Positron Emission Tomography (Guidelines).

3. Shields Imaging of Massachusetts, LLC has demonstrated demand for a mobile PET unit to serve South Shore Hospital, UMass Memorial Medical Center, and Baystate Medical Center, as discussed under the Health Care Requirements factor of the staff summary.

4. The project, with adherence to a certain condition, meets the operational objectives of the Guidelines.

5. The project meets the compliance standards of the Guidelines.

6. The recommended maximum capital expenditure of $2,564,000 (February 2001 dollars) is reasonable, based on the price quote from the PET equipment vendor, which, when the trailer is excluded, is similar to comparable projects.

7. The recommended operating costs of $3,135,291 (February 2001 dollars) are reasonable for a freestanding mobile PET service.

8. The project is financially feasible and within the financial capability of the applicant.

9. The project meets the relative merit provisions of the Guidelines.

10. The project, with adherence to a certain condition, meets the community health service initiatives of the DoN Regulations.

11. The Mark R. Taylor, Mary T. Sweeney, and Stephen M. Weiner Ten Taxpayer Groups (TTGs) registered in connection with the proposed project. The Brockton Ten Taxpayer Group originally registered as well and requested a public hearing, but subsequently rescinded its request on August 6, 2001, and withdrew as a TTG on August 7, 2001. The Taylor TTG submitted written comments, which indicated that there was excess capacity at New England PET Imaging System in Methuen, a DoN exempt physician practice. However, Staff noted that this excess capacity has not eliminated demand for existing PET services at MGH and Dana Farber, as indicated by patient waiting times at these facilities. Staff further notes that Shields has projected demand for PET services based on the patient populations of the three host hospitals: South Shore, UMass Memorial, and Baystate, all of which are located further from Methuen than the Boston Pet services. Therefore, it is unlikely that Shields' patients would chose instead to use the services of New England Pet Imaging System.

12. This project is one of four comparable applications filed by Shields Imaging of Massachusetts LLC, Children's Hospital Medical Center, Brigham and Women's Hospital, and Beth Israel Deaconess Medical Center. When considered alone, all of the applications are capable of being approved, since each has demonstrated demand for PET services. A detailed comparability analysis was not undertaken since the four applications meet all the review factors of the PET Guidelines.

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The meeting adjourned at 11:10 a.m.

Howard K. Koh, M.D., M.P.H.
Chairman

LMH